REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-53 are pending. Claims 1-15 and 19-53 stand withdrawn as directed to non-elected subject matter.

Claim 16 is amended herein. Claim 18 is canceled without prejudice or disclaimer.

Specification

The specification is amended herein to address informalities, further to the Office Action, page 6.

Claim Objections

Claims 16 and 17 stand objected to as the scope of the invention is allegedly drawn to a method of contraception in a female subject. Claims 16 and 17 are amended herein to recite a female subject but the claims are not limited to females.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 16-18 stand rejected under 35 U.S.C. § 112, first paragraph, as the claims allegedly fail to comply with the enablement requirement. The Office argues that the claims, as directed to contraception, must prevent conception 100 percent of the time. Applicants note that few forms of contraception are always 100 percent effective, as noted by the Office, but are still largely effective. However, in the interest of expediting prosecution, claims 16 and 17 are amended herein to recite a method of reducing the incidence of conception.

The Office further states that undue experimentation is needed to determine which claimed agents effect CG activity. Applicants traverse.

Assays and tests for determining the activity and potency of synthetic fragments of molecules, such as CG and other molecules, exist and are known in the art, including those developed by the present inventors.

References describing these assays are set forth below, where, for example, fragments of CG, LH receptor, other hormones and other receptors were tested for their capacity to bind to the receptors, activate receptors and suppress receptors.

- Roche et al. (1992) Identification of hormone-binding regions of the luteinizing hormone/human chorionic gonadotropin receptor using synthetic peptides. *Endocrinology* 131:268-274;
- Keutmann et al., (1989) Role of the beta 93-100 determinant loop sequence in receptor binding and biological activity of human luteinizing hormone and chorionic gonadotropin. *Mol Endocrinol* 3:526-531;
- Morbeck et al. (1993) A receptor binding site identified in the region 81-95 of the beta- subunit of human luteinizing hormone (LH) and chorionic gonadotropin (hCG). *Mol Cell Endocrinol* 97:173-181;
- Gardella et al. (1995) Parathyroid hormone (PTH)-PTH-related peptide hybrid peptides reveal functional interactions between the 1-14 and 15-34 domains of the ligand. *J Biol Chem* 270:6584-6588;
- Santa Coloma et al. (1990) Identification of follicle-stimulating hormone receptor binding region in hFSH b(81-95) using synthetic peptides. *J Biol Chem* 265:5037-5042; and
- Leng et al. (1996) D-amino acid substitution of residues 32 to 46 of the glycoprotein hormone common alpha-subunit: development of a synthetic glycoprotein hormone antagonist. *Pept Res* 9:188-194.

Claims 16, 17 and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification purportedly does not provide adequate written description of the agent, other than CG itself. The Office asserts that Claim 17 does not define any structure, and that while a CG protein could be made, there is purportedly no recitation of what constitutes biologically active fragments or other synthetic or natural compounds. As noted above, the specification and art provide description as to a biologically active fragment as claimed.

Thus, Applicants submit that simply identifying an appropriate fragment for inhibiting and affecting CG activity or CG interaction with the exoloop 1, exoloop 2 or exoloop 3 domain of the LHR would be within the purvue of the skilled artisan, and is supported by what is known in the art and specification as-filed.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 16-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Talwar et al. (*Proc. Natl. Acad. Sci.* 91:8532-8536 (1994)) ("Talwar"). Talwar purportedly teaches a composition comprising a biologically active fragment of CG (βhCG) that neutralizes the bioactivity of hCG and reduces incidence of conception.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226,1236, 9 U.S.P.Q.2d 1913,1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants submit that Telwar does not recite each element of the present invention.

Telwar is directed to a pregnancy vaccine. A vaccine is irreversible, and an effective vaccine would irrevocably sterilize a patient. In this regard, sterilization is an undesirable effect for many patients wishing to utilize contraception. The claims as amended are directed to a method of reducing the incidence of pregnancy in a subject. A vaccine would sterilize a patient.

Applicants also note that a vaccine using CG could attack the pituitary gland that expresses LH and FSH, as they share a similar structure and amino acid sequence with hCG beta subunit. If the pituitary gland is attacked and damaged, it will disrupt the secretion of many other pituitary hormones including growth hormone and may damage the entire body. Thus, the vaccine of Telwar is not tenable, and does not disclose the present invention.

In light of the above, Applicants request that this rejection be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date: April 27, 2006

By: _____
Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620